IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Daren L. Stewart et al.	Examiner: John P. Lacyk
Application No.: 10/683,885	Group Art Unit: 3735
Filed: October 10, 2003	File No: 667P
For: APPLICATOR FOR RADIATION TREATMENT OF A CAVITY	Tiburon, California

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE, ON THE DATE INDICATED BELOW, AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313

DATE OF DEPOSIT APRIL 22, 2008

THOMAS M. FRYBURGER, REG. NO. 27,063

SIGNED

DATE 4-22-08

DECLARATION UNDER 37 CFR 1.131

This is a declaration to show the inventors' prior conception of the invention before the effective filing date of Lubock Patents Nos. 6,955,641 and 6,923,754, coupled with diligence in continued work on the invention through filing of this application October 10, 2003. The effective filing date of both patents apparently is November 6, 2002.

Daren L. Stewart, Paul A. Lovoi, Thomas W. Rusch, Alex Lim and Darius Francescatti declare and state as follows:

1. We are the inventors in this application, as listed in the declaration as filed.

2. We conceived the invention of the claims under consideration, claims 41-50 and claims 53-137, prior to the effective filing date of Lubock Patents Nos. 6,923,754 and 6,955,641, that is, prior to November 6, 2002. We were diligent toward developing this invention and toward reducing it to practice from a time prior to November 6, 2002 until the filing of the current patent application on October 10, 2003. We worked continually on all the many aspects of the applicator project. We were under pressure from our CEO and our company's investors to complete the balloon applicator, x-ray tube, controller and other components of the brachytherapy system to be launched and marketed. The balloon applicator itself included a number of different aspects, drainage being one of them. Ongoing work toward reducing the applicator to practice included many non-drainage aspects which had to be resolved before all of these features could be integrated into an applicator that could be built and tested. Two of the inventors were assigned to work on the applicator for more than a year. All aspects had to be addressed to arrive at a final design because some features would have an effect on others. All balloon applicator development from prior to 11/6/02 until the filing of our patent application included the concept of drainage, considered and then firmly incorporated, including the concept of suction holes in the applicator shaft to withdraw fluids near the balloon, and the

applicator in the system as ultimately launched and marketed has this feature.

3. An entry in the notebook of Thomas Rusch, 10/7/02, attached hereto as Exhibit A, regarding a brachytherapy applicator which is the subject of this patent application, states: "Consider having a drain port/membrane on our applicator and catheters, if necessary, to remove seroma. Use a std. squeeze bottle to apply suction force." The entry was made 10/7/02 to memorialize a discussion at a meeting with D. Francescatti and others 10/6/02. Though not the first conception of the invention of a balloon applicator with provision for drainage from the space between the balloon and the tissue of the cavity wall, this entry shows we were considering this improvement at least as early as 10/6/02.

4. Exhibit B is entitled "Xoft microTube Breast Brachytherapy System Preliminary Marketing Requirement Specifications", dated 11/12/02. The document outlines specifications of the system including the applicator and its shaft and balloon and relates to launch of the applicator project.

5. A further entry in the notebook of Mr. Rusch, attached

here as Exhibit C, is dated 11/15/02. This entry discusses balloon behavior for a balloon applicator, and says questions the impact on dose of a contrast medium in the balloon.

6. Exhibit D is an unsigned version of a confidential disclosure agreement, in preparation for signatures, dated 11/27/02 between Xoft microTube, the assignee herein, and Polyzen, Inc., for the purpose of discussions on applicator design.

7. Exhibit E, 12/3/02, from the laboratory notebook of Paul A. Lovoi, discusses balloon information of Proxima and other brachytherapy balloon applicators. Includes notes on balloon design, shaft design and wound management, external and internal. Includes notes on processes for making brachytherapy balloons. A note at the bottom says "1/2 psi will stop fluid flow." This refers to small lumens in the applicator shaft for draining seroma, and overcoming the effects of surface tension in the small lumens. These were notes taken during a telephone conversation with a vendor. This was part of ongoing work on brachytherapy balloon applicator design.

8. Exhibit F, one page from internal PowerPoint presentation last updated 12/16/02. Entitled "Apollo Therapy

System" (with date October 2002), sheet schematic block diagram showing brachytherapy system, with applicator, x-ray source, controller, etc.

9. Exhibit G is another page from the same PowerPoint presentation (last updated 12/16/02) entitled "Needed Disclosures - System". This page outlines the different aspects of the brachytherapy radiation system being developed by Xoft microTube including the applicator which was to have seroma drainage and vacuum conformity of tissue.

10. Exhibit H, 2/6/03, three pages, laboratory notebook of Daren Stewart, pages 41-43, refers to the balloon applicator project. The notes outline aspects of the applicator project and list "Jackson Pratt Drainage device" as a kit component (p. 41). Page 42 further describes the Jackson Pratt drainage device, an off the shelf component, saying it must "mate to the J-P port on the applicator."

11. Exhibit I, 2/7/03 (date halfway down page), entry in notebook of Steve Hansen, non-inventor employee of assignee involved in management of project. Notes of a staff meeting for planning on this project. Includes notes of telephone conference with D. Francescatti, with Daren Stewart, Alex Lim, Steve Hansen

and Tom Rusch present. Says "Idea of Dr. Francescatti – 6 to 8 feeder tubes that feed a main drain lumen. This will drain fluid & pull tissue to the applicator." The notes further state "Use JP [Jackson-Pratt] bulb attached during treatment." This shows the intention of the inventors to include the feature of drainage and suction in the applicator, and shows continuing work on this aspect, so that suction applied to the applicator will drain fluid and pull the cavity tissue to the applicator.

12. Exhibit J, 2/18/03, two pages, notebook of Daren Stewart, pages 45 and 46, includes notes of Daren Stewart regarding a meeting with Alex Lim, Tom Rusch, Steve Hansen and Horst Adam concerning a 2/7/03 telephone call with Darius Francescatti. The notes discuss seroma drains for breast surgery. Further, the notes on "follow up from phone call on 2/7/03 with Darius Francescatti" discuss the drainage feature in the applicator, and several internal meetings that were held after the telephone conference with Dr. Francescatti. The notes confirm agreement "that a substantial effort needs to be made to include a drainage system in the applicator to remove fluid for patients who experience extreme buildup as well as prior to a treatment dose", and also notes "This item to be included in any future patent disclosures."

13. Exhibit K, 2/24/03, two pages of Stewart notebook, relating to design of applicator with balloon. Notes mention two port hub and center port to be used for drainage. Following page, also 2/24/03 ("MDM recap") says "Talk to Steve re: ports on inflation & suction (Need to be different)").

14. Daren Stewart notebook pages 26-27, Exhibit L, dated 3/21/03, discussing design of applicators, contrast medium in balloon, sourcing of balloons, shape and skin thickness of balloon, indicating continued work on balloon and balloon applicator.

15. Exhibit M, 3/26/03, Daren Stewart notebook entry, "Xoft Controller: Notes to self", discussing balloon shape and correlation of balloon shape with patient need, showing continued work on balloon and applicator.

16. Exhibit N, 4/2/03, Daren Stewart notebook entries, page 33 regarding different aspects of entire system to be constructed and marketed, including the controller or console and the applicator. Correlating correct applicator to patient.

17. Exhibit O, 4/30/03, Daren Stewart notebook entry regarding balloon design, mentioning ribs inside the balloon that

could potentially control the shape of the balloon. Shows continued work on balloon design, all aspects of which had to be designed and resolved prior to building and releasing the system.

18. Daren Stewart notebook, Exhibit P, three pages, entries dated 5/14/03 and 5/15/03, mentions "balloons with barium", goal of animal testing, other aspects of applicator in balloon design.

19. Exhibit Q, Stewart notebook dated 5/28/03, "Post Dry Run Animal Study Download". Mentions barium loaded balloons, and radio opaque markers on balloon, relative to balloon design, showing continued work on balloon design.

20. Exhibit R, 6/12/03 entry in Stewart notebook on balloon applicators, and x-ray imaging trials with balloons having contrast medium.

21. Exhibit S, 6/17/03, Daren Stewart notebook entry. "Meeting with Robert Bley". Mentions balloon and drainage in context of balloon design. Mentions Accusil, a balloon manufacturer.

22. Exhibit T, 6/18/03 entry in Stewart notebook, two pages, regarding final design of applicator and other components

of system to be produced. Mentions details of the hub of the applicator and balloon sizes, balloon stiffener. Second page of this two page exhibit mentions drainage; drain.

23. Exhibit U, 7/8/03 entry in Stewart notebook, concerning design of balloon, specifically balloon shapes and sizes to be made available.

24. Exhibit V, 7/9/03 entry in Stewart notebook "Applicator to do items". Mentions balloon drawings, "more shapes"; contrast info, tests; schedule for molded parts from Accusil; notes of phone call with Accusil regarding balloons with ribs and variable thickness.

25. Exhibit W, 7/16/03 entry in Stewart notebook, "meeting w/ Stellartech" list of matters to address regarding design of applicator, and mentions testing with all different sizes of balloons.

26. Exhibit X, engineering drawing dated 7/17/03 and shown as produced by Alex Lim. The drawing, numbered 710002, shows the applicator with a hub at the proximal end including three ports, one being a drainage port. A deflated balloon is shown at the distal end, and drainage ports are indicated in the applicator

shaft, seven drain holes at each of distal and proximal positions relative to the balloon.

27. Exhibit Y, engineering drawing showing applicator, without legend. This drawing, which we believe was produced at the same time or within a few days of Exhibit X, and similar to Exhibit X, shows the same applicator with the two sets of drain holes on the shaft distal and proximal of the balloon, but in this case with the balloon inflated.

28. Exhibit Z, 7/22/03, "Applicator Brainstorming Meeting" agenda prepared for meeting attended by inventors Paul Lovoi, Daren Stewart, Alex Lim and others. Typed agenda notes "Applicator with Drain/current design/textured balloon/multiple ports". Mentions other aspects of applicator design including balloon expansion limiter for size control. This copy has handwritten notes.

29. Exhibit AA, 7/22/03 entry in Daren Stewart notebook, "Applicator Patent Submission Mtg.", notes on the 7/22/03 meeting outlined above and indicating a list of features of the applicator was to be generated for the preparation of a patent application.

30. Exhibit AB, 7/25/03 entry in Stewart notebook, again relating to applicator balloon sizes, and with table of volumes versus dimensions.

31. Exhibit AC, 8/13/03 entry in Daren Stewart notebook, page 67, describing plan for animal testing with multiple shaped balloons, eight animals, and noting human studies to follow.

32. Exhibit AD, 8/14/03 entries in Stewart notebook, two pages, pages 68-69, "Animal Study #3 Preparation Meeting" further planning for animal testing/studies using balloon applicator designed pursuant to invention, with notes on scheduling, applicator parts to be ordered from Accusil, sizes of balloons and preferred barium.

33. Exhibit AE, 8/29/03 and 9/3/03 entries in Daren Stewart notebook, "Balloon Applicator Hazard Analysis", two pages (pp. 76-77). Explores different types of hazard, failure or problems that could occur with balloon and relates to balloon design, instructions for use.

34. Exhibit AF, 9/8/03 entry in Stewart notebook, p. 81, "Accusil agenda". Has notes on shaft thickness, balloon sizes and thickness of material, inflation valve for balloon, and other

issues to be raised with Accusil, the balloon maker. Shows ongoing work on improving the applicator.

35. Exhibit AG, 9/10/03, 9/11/03 and 9/12/03 entries, entitled "1st Day Goat #3", "Back @ Lychron", and "Lychron (animal testing laboratory), in Stewart notebook, three pages. Notes describe procedures used on goat, size of balloon and liquid filled into balloon, and results observed.

36. In September 2003 we had communications with our attorney, Thomas M. Freiburger, for preparation of a patent application on the applicator with its various innovative features. We received a first draft of the application from the attorney in about mid-September. On 9/22/03 we received a fax from the attorney, with an updated draft of the patent application, which was primarily the same as the application as filed.

37. The patent application was filed on October 10, 2003. Signatures on the declaration were provided later.

We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 4/22/08

Daren L. Stewart

Date: 4/22/08

Paul A. Lovoi

Date: 4/22/08

Thomas W. Rusch

Date: 4/22/08

Alex Lim

Date: _____

Darius Francescatti

We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date:_____ Daren L. Stewart

Date:_____ Paul A. Lovoi

Date:_____ Thomas W. Rusch

Date:_____ Alex Lam

Date: 22 Apr 08 Darius Francescatti, M.D.

10/3/02 Nijazi – SH, MF, TR →

- Schedule from here to market release →
- Don't get rearcissed w/o Nijazi's approval
- Think about manufacturability →

tubes (?) → 1 ch.) ; S/N (3 ch.)

10/3/02 Vince - 408-331-3124

- Test controller leakage → ramp to 40kV → Bill will be there tomorrow →
- Filament 100-200 ma on 10 Ω resistor →
- Voltage between chassis & earth, current between chassis & earth

D
0/1 b'day ining

Tube Meeting –

- Take p.s. to Bill tomorrow – upgrade to 40kV and determine reason for filament arcing.
- LTD may be able to give us injection molded ends

10/7/02 Tube Meeting –

(225 filaments ?)

- Characterize filament circuit and measure with current probe.
- Weld bearing is proceeding → no/not hairpin / filaments twisting in 2-hole tubes.
-

Vince –

- SW has things to be developed
  - ① Need HV supply and current driver under SW control, to do this need the interface board working. ② Need a filament current source subcct (from Bill P.
- SW will concentrate on file system then data logging
- Hold on GUI work until we get more feedback from Michael →

ting)

Critical path → fil. supply and HV supply prototypes to test →
- need HV relay to test arcing →

Meeting with Lorraine Tafra, Dawn Francheschetti and Ken Blum – 10/4/02

⊛ Dawn: Consider having a drain port / membrane on our applicator and catheters, if necessary, to remove SBROMS. Use a std squeeze bottle to apply suction force.

J. Rauch 10/7/02

c. Raleigh 2-22-07

Xoft microTube Breast Brachytherapy System
Preliminary Marketing Requirement Specifications
November 12, 2002

In-Vivo Device Position Check (QA): External imaging: Fluoroscopy, CT or ultrasound.
Target Tissue Depth: 1 cm at 100% Isodose Point.
Venues of Use: Unshielded Operating Room, Unshielded Treatment Room or Radiation Oncology Suite.
Method of Application: Open cavity or percutaneous.
Fractionation Schedule: Single fraction IORT, single fraction percutaneous, post-pathological assessment or Multi-fraction (up to 10 fractions) delivered over up to 5 days post-pathological assessment.
Target Tissue Dose: Single fraction dose of 18 Gy; Multi-fraction dose of 34 Gy over 10 fractions (3.4 Gy/fraction).
Treatment Delivery Time: Single fraction IORT less than or equal to 30 minutes; Single fraction percutaneous, post-pathological assessment less than or equal to 45 minutes; Multi-fraction less than or equal to 10 minutes per fraction.
Surface to Target Ratio: Applicator surface to 1 cm treatment depth, less than 2.50.
Dose Homogeneity Index: Minimum of 0.70.
Maximum non-Conformability Post Installation: Total of 30% of candidates (5% of treated tissue volume)
Maximum Tolerable Device Failure Rate: 10% for all reasons combined.
Edema/Drainage Management: Jackson-Pratt Complete Closed Wound Drainage System
Maximum Tumor Size: 2 cm
Minimum/Maximum Cavity Size: 4 cm; 5 cm
Maximum Acceptable Trocar Size: 8 mm
Device Shaft Outer Diameter: 6 mm, maximum
Device Shaft Length: 15 cm, maximum
Balloon Inflation Connector: Luer fitting
Maximum Balloon Inflate/Deflate Time: 30 seconds
Patient Eligibility: >50 years of age, unifocal disease, N0, M0
Patient Ineligibility: Invasive or in-situ lobular carcinoma, DCIS, EIC, skin or chest wall involvement, breast unsatisfactory for brachytherapy, last breast surgery more than 8 weeks prior to planned brachytherapy.
Minimum Cup Size: B
Margin Status: Microscopically negative surgical margins >2 mm
Distance Edge of Cavity to Skin: 5 mm, minimum.
Product Conformability Range: 4-5 cm
Pre-Treatment Dose/Rate Measurement Capability Built in: Yes
Sterilization: One time sterile disposable.
Reusability: Disposable with provisions to prevent reuse, except for multi-fraction use in the same patient.
Minimum Shelf Life: One Year.
Marketed Countries: US, Europe and Japan.
Average Selling Price: $3,000 US.
Cost of Goods: $300/kit, maximum.

EXHIBIT C

236

- format
- Change docs for monday ←

11/5/02 Pre-DRS Discussion → PS, KY, RN, PL, AL, PF, CR, ED, PV, NB, FJ, GR,

- Mandy won complete revisions. All afternoon Monday ⊛
- Need more info about sterilization for multiple uses ⊛
  - (Up to 10 sterile sheaths) ⊛
- ⊛ - What is the impact of contrast medium on dose? (definitive)
- Balloon: how does major axis length/ diameter during inflation ← ?

Jim Morrison - Call him or email w/ update ⊛

- Turn on 2 Jan 1, modules late Feb or March - staffing up with addl engineers
- Situation to us in mid-to-late December for BM review ⊛
- Development cost ≈ $50K / $15K to X-ft

Pre-DRS (cont'd) →

- Include sterilization in DRS ←
- Include dielectric constants as part of the spec
- Still trying to have a low risk process
- Look at filament/light bulb mfg machines ⊛
- Get IEC docs that are relevant ⊛ see Khalil

11/18/02 Product Design Team Meeting - PL, PS, NB, MW, SH, KY, TR

RDP-0017 - Design Control
- Check out procedure for Pressure (total turnaround time) ⊛
- ✓ Look at catheter procedure spec.

11/18/02

C. Robert 2.22.03

CONFIDENTIAL DISCLOSURE AGREEMENT
Between
POLYZEN, INC., P.O. BOX 1487, Cary, NC 27512
And
XOFT MICROTUBE, 49000 Milmont Drive, Fremont, CA 95070

This agreement is made this 27th day of November, 2002, by and between Polyzen, Inc. and Xoft microTube.

1. Purpose. The parties wish to explore a business opportunity of mutual interest and in connection with this opportunity, each party may disclose to the other certain confidential technical and business information that the disclosing party desires the receiving party to treat as confidential.

2. Each party (the Producing Party) may disclose to the other (the Recipient) certain trade secrets and confidential INFORMATION relating to specific design specification and fabrication of a certain specific device as listed below to Recipient in writing, tangible samples and/or orally in sufficient detail for Recipient to fully evaluate said disclosure:

Cathaters and Applicators for Brachytherapy

3. To be protected under the agreement, the term INFORMATION shall mean all business plans, information, data, facts, methods, projects, procedures and processes of manufacture, tooling and equipment, materials, compositions of matter, products and components of products, commercial information relating to suppliers, customers, marketing, sales, financial information, patent and trade secrets, proprietary know how and manufacturing process, research and development samples, management protocol, product designs, product development strategy, or such information which becomes known to Recipient as a result of access granted to Producing Party facilities, and which is disclosed to Recipient in tangible, documentary, or graphic form, and conspicuously labeled as confidential information of Producing Party. Oral disclosures for which protection is sought must at the onset be clearly identified as proprietary information and be documented in detail, labeled as above and submitted to Recipient in written and graphic form within (30) business days after disclosure.

4. Recipient agrees that for a period of ten (10) years from the date of this agreement, he/she/ any agents and representatives will maintain in confidence the INFORMATION disclosed and will not use the INFORMATION for the ten (10) years period other than for evaluation purposes until or unless a formal written contract is entered into providing the terms and conditions of such use, all such information in tangible form and copies thereof shall be returned to producing party upon written request.

5. The obligations of Recipient shall not extend to all or part of the INFORMATION:

   (A) which is in the public domain or publicly known or available prior to the date of disclosure; or

   (B) which can be demonstrated to have been in the possession of Recipient or affiliate(s) or available to Recipient or affiliate(s) from another source prior to disclosure; or

(C) which becomes part of the public domain or publicly known or available prior to the date of publication or otherwise, not due to any unauthorized act or omission on the part of the Recipient or affiliate(s); or

(D) which is rightfully received by Recipient from a third party without restriction of confidentiality thereof.

6. That Recipient agrees, except as otherwise expressly authorized by the Producing Party, not to make copies or duplicates of any confidential INFORMATION for a third party, other than those employee(s), agent(s), or affiliate(s) to whom information is necessary for evaluation purposes, or not to derive or attempt to derive, by reverse engineering, disassembling, decompiling, or otherwise, any portion of the confidential INFORMATION, which has not been previously disclosed by the Producing Party to Recipient. Recipient agrees for the benefit of the Producing Party to bind its employee(s), agent(s) and affiliate(s) receiving any INFORMATION for evaluation purposes, to observe confidentiality and restricted use obligations in respect of such INFORMATION, under terms no less stringent than those imposed by this Agreement on the Recipient.

7. Both parties agree that no right or license under any patent or trade secret now or hereafter owned or controlled by either party is granted to the other party by this agreement, nor is any such right or license to be implied from the disclosure by either party on its confidential INFORMATION to the other party except as expressly set forth herein.

8. Both parties agree that due to the unique nature of the confidential information there can be no adequate remedy at law for any breach of Recipient's obligations under these agreements, thereby resulting in irreparable harm to the Producing Party. Therefore, upon any such breach the Producing Party shall be entitled to appropriate mandatory or negative injunctive relief in addition to whatever remedies it might have at law.

9. The undersigned signatures represent that each has the actual authority to enter into the present agreement on behalf of his company.

Xoft microTube

By:_____

Name: Paul Lovoi

Title: President and CEO

Date: November 27, 2002

Polyzen, Inc.

By:_____

Name: Tilak M. Shah

Title: President

Date:

TILAK POLYZEN 12/3/2002 EXHIBIT E

(TEKAK)

BALLOON MANUFACTURING - PROXIMA

40+ PEOPLE 1991 FOUNDED -
15K ☐ BUILDINGS 52K☐ READY NEXT MARCH - MOVING IN
5 - 6 MAJOR 20 SMALLER CUSTOMERS -
30 - 40 PROJECTS / YEAR 1MM / YEAR GAL BAG.
STENT 300 - 400 / MONTH
BALLOON DESIGN 100,000 / YEAR
SHAFT DESIGN 1,000 / MONTH
MATERIALS ~3,000 / MONTH BRACHYTHERAPY
WOUND MANAGEMENT - EXTERNALLY - INTERNAL
THEY WILL MANUFACTURE THE CATHETER TOO
MARKER - FOR IMAGING
3 PROCESSES FOR MAKING BALLOON LOW PRESSURE 1.6 S 1.4 P.
1) DIP MOLDING - SILICONE - POLY U. LIMITED NECK TO BODY
2) LOW COST - SIMPLE SHAPE - BLOW MOLDED NECK THICKNESS THICK - BODY
3) FILM - THERMO FORMED - WITH HAIRLINE SEAM - SEAM IS INSIDE
P.U.
MOST BRACHYTHERAPY IS DIP MOLDED
NEW PROCESS
RESTING STATE - 2mil EXPANDED.
WALL THICKNESS OF FILM - 3 - 4 mils VS 20 mils for dip molding
2 psi TO EXPAND 6 - 8 psi BURST

$ COST COMPARISON 100 / MONTH TO START
$25 / BALLOON
$50 - $60 / FINISH

COAT WITH LOW COF - APPROVED BY
WILL HELP WITH ☐

	PREFERRED	ALSO
SILICONE -	ETO	GAMMA
PU	GAMMA	ETO

RADIO OPAQUE FILM LAMINATE

$10K - $15K FOR $1.5 $1.8

½ psi WILL STOP FLUID FLOW.

Low-Pressure Balloons

Polyurethane alternatives to low-pressure latex balloons are available in 1:10, 1:15, and 1:20 neck-to-body ratios. The balloons can be produced in any size and configuration and as small as 0.050 in. The units are

fully three-dimensional, exhibit a nearly invisible seam, and can be produced in thicknesses from 1 to 10 mil. All polyurethane films are suitable for and meet Class VI med-

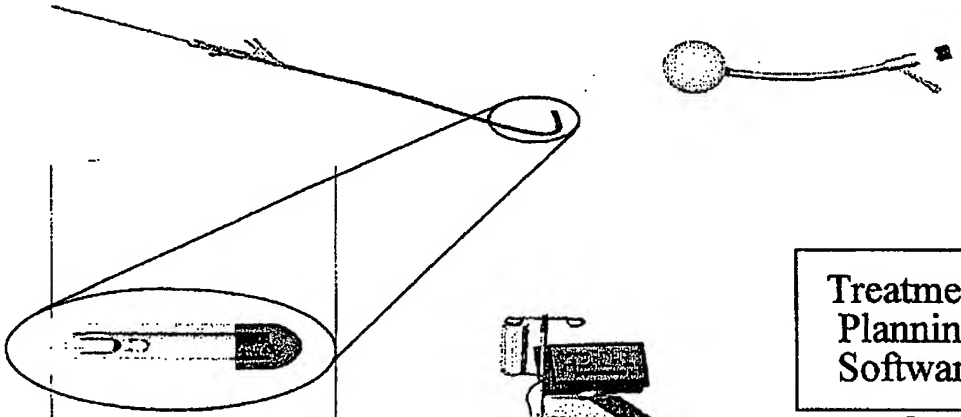
Xoft microTube

Apollo Therapy System

Cooling Catheter

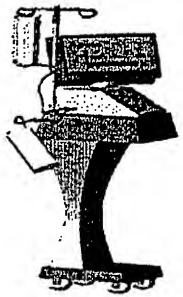
Single Source Applicator

Package, Sterilize & Label



Disposable

Treatment Planning Software



X Ray Source

Controller

Xoft microTube Apollo Therapy System

Xoft microTube Proprietary

EXHIBIT F

Xoft microTube

Needed Disclosures - System

- **Interconnecting Sleeve**
  - **Fittings for No Error Attachment (C)**
  - **Design Features that Minimize Straightening Errors and Friction (C)**
- **Applicator**
  - **Seroma Drainage (C)**
  - **Radio-opaque marking schema (C)**
  - **Vacuum conformity of tissue (C)**
  - **Method for verifying distal positioning of x-ray catheter (C)**
- **Control Console**
- **Software**
- **Dosimeters**
  - **Position and use in arrays (NG)**
  - **Connection and cabling (NG)**
  - **Wireless operation (F)**
  - **Dual sensitivities per chip (NG)**
  - **Use for re-verifying source location in multi-fraction (C)**
- **Algorithms**
  - **Mapping of cavity (NG)**
  - **Mapping of cavity location (NG)**
  - **Gap or seroma detection and location (to avoid repeated imaging) (C)**
  - **Treatment optimization (NG)**
  - **Rotary treatment (F)**
  - **Real time treatment algorithms (F)**

EXHIBIT H

3 of 6

2/6/03

Applicator Project:

- Applicator Kit
  - → Applicator (Device)
  - → Obturator
  - → Peel Away Introducer Sheath
  - → Jackson Pratt Drainage device
  - → Balloon Inflation Mechanism

- X-Ray Source Catheter
  - *

- Applicator Shaft Extension
- Cooling Tubing Set
- Radiation Shield

Meeting:
Important dates

April 15th show & tell samples
June Animal study

./2002

Disposable Kit Interaction dependencies.

- Applicator: Stand alone device. This is my reference point.

- Obturator: A small straight section of plastic with a hub should fit down the internal lumen of the applicator.

- Peel Away Introducer Sheath: The applicator must fit through the I.D. of the sheath with little resistance by pushing the obturator filled applicator.

- Jackson Pratt drainage device: This device is an off the shelf component. It can have a variety of connector sources. The connector must mate to the 5-7 port on the applicator.

- Balloon Inflation Mechanism: The balloon inflation mechanism will more than likely be a large CC syringe. There are a number of manufacturers of off the shelf valves (Helkey Roberts Inc.) that make valves that are designed to fit Luer Lok & Luer Slip tip syringes. They are commonly used for applications such as feeding devices. Once a valve is chosen, the balloon inflation mechanism can be designed and determined.

- X-Ray Source Catheter: The X-Ray source catheter must slide down an internal lumen on the applicator. There must be sufficient clearance between the O.D. of this catheter and the I.D. of the lumen in the applicator to provide an easy (as close to frictionless) insertion & retraction

- Applicator Shaft Extension: This piece must attach to the applicator via a custom or standard connector. It will

- Cooling Tubing Set: The cooling tubing set must connect to the X-Ray Source catheter in two places & to an input coolant source.

- Radiation Shield: This will be a stand alone component. It could be included in each kit, but it could also be included with each system.

SAB Meeting Morning

Horst, Mirja, Steve

EXHIBIT I

- What can be done by April 15th?

29JAN03

Staff Mtg. - noon
Vaisala Horst A. Steve H.
Pete S. Tom R. Amy C.

2pm - IP meeting

Steve H. Paul L.
Horst A. Tom R.

Write Applicator Disclosure - Alex.

07FEB03

T-con with Dr. Francischetti

Dave Stewart, Alex L., Steve H., Tom R

Idea of Dr. Francischetti

↳ 6 to 8 feeder tubes that feed a main drain lumen. This will drain fluid & pull tissue to the applicator.

- Use IP bulb at the end during treatment.

Serona the crystalline of serum.
There has not been any clotting if no blood is present.

Proxima experience — variable amount of serona — 5 hrs or more.

18Feb03

Catheter Mtg.
HA, GR, AL, TR, SH, Dave Stewart.

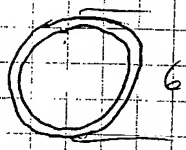
① Do we need to provide a trocar.

EXHIBIT J

2/18/03

Applicator meeting w/ Alex, Steve, Horst, Tom

- Applicator shaft O.D. stay with 6 mm ?
- Balloon with ridges
- Serome drains (breast surgery)
- Stay w/ 6mm on O.D.



- 2 extrusions vs 1 extrusion

2/18/03

Follow up from Phone call on 2/7/03 with Darius Francescatti.

Drainage feature in applicator. After the phone call a few internal meetings were held internally where the method and need for drainage integrated into the applicator ~~would~~ were discussed. It is now agreed that a substantial effort needs to be made to include a drainage system in the applicator to remove fluid for patients who experience extreme build up as well as prior to a treatment dose.

This item to be included in any future patent disclosures.

Dawn Stewart

Other Lab Note Book Used until next log in date.

2/24/03 Xoft

Acust: Assembly
Sterile pkg.

→ Design option

- 2 port hub.
- Use center port for drainage between treatments
- Use a sheath over X-Ray catheter for treatment (this becomes disposable for every treatment)

Advantages
- larger suction lumens
- easier/manufacturable device.

TFE for a sheath .001 tolerance

Coextruded X-Ray catheter extrusion with something other than metal that will give the "rigidity" decron, kevlar, fiber type material,

2/24/03 MDM recap

- Simtec (partial polymerization)

Talk to Steve re: Ports on inflation & suction (Need to be different)

EXHIBIT L

3/21/03

Conf. call.

Dr. Marty Keisch

→ delays with new applicators. No human data available.

→ 1-2 weeks post op ideal.
- healing, foreign body, etc., cav. ↑ still there?

7% dilution of contrast medium.
Mix it themselves.

insert in an exam room.

Ultrasound or plain films.

3/21/03

Meeting update:

Silicone molds with lesions, with cavities.

Who was it that had them?
How much do they cost?
How long will they take to get?
Do we need to fabricate our own?

Make an oblong balloon or an extrusion.

Do we have all the tools needed?
Trocars, sheaths etc.

- abrasive injury
  - suture material
  - ribs
  - charred tissue
  -

- Balloon inflation
  - ↳ check port,

- Skin thickness.

- We have an advantage in that we can wipe down our X-Ray catheter.

3/26/03

Xoft

Controller 8

Notes to self:

- Interactions with applicator, x-ray catheter, cooling set etc.

? → 300 uns 6/day $\sqrt{300}$ 50 days ?

? → Applicator I.D. Serialized? or by lot?

? → Flow sensor?

? → Bar code reader imbed it in the pull back head?

→ Applicator determines balloon shape. We need to verify or determine what applicator is in the patient??

→ Correlate the balloon shape per patient by bar code on the packaging.

→ Multi stick labels in applicator package. One gets stuck on chart & then read by reader on console.

4/2/03

Controller (Console) Mtg.

→ See Tom's notes from last ~~Weeks~~ mtg.

- CSM nursing Ruth McCracken
- Torso: buy one?
  borrow one? Call Vince
- Cart? IV pole?
- Comment on Tom's notes
- Applicator
  → I.D. Strip from packaging
  Place on patient chart?
  • Read barcode prior to each treatment & then confirm on screen that it is correct.

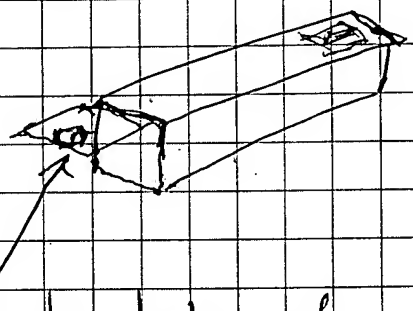
- X-Ray Catheter
  → I.D. for the source, mounted on the source connector? or mounted on the x-Ray catheter hub?

  → what kind of I.D. should we use? chip, barcode, etc.

  → Manufacturing concerns when de

4/20/05. cont'd

→ Connector on applicator, what does it look like? What does the nest on the end of the pull back arm look like.



applicator hub nest

→ Dosimeter. Where does this go? How will it work?

Console spec. current bird is just over $1 million

→ Time & material job with best guess estimates. Not laid out as a fixed price endeavor.

→ Ribs inside balloon could potentially control shape.

5/14/03

SAB download meeting

Thurs. 1:30 - 4:00 ⇒ @ BC Tech, Do I want to attend?

Stellartech, BC Tech quote?
Michael Forman ⇒ used to work @ Xoft. Is now @ BC Tech & is working on the quote

- Stenographic download.
  - make a list of all the things I heard in my section.

3 categories
- Very general in technology
- More specific
- Very specific in regards to stuff

→ Footswitch? Do we need one?

X Ruth McCracken
Thank you letter for dummy. (Done)

Animal mtg. @ 9:30
Download mtg @ 10:30

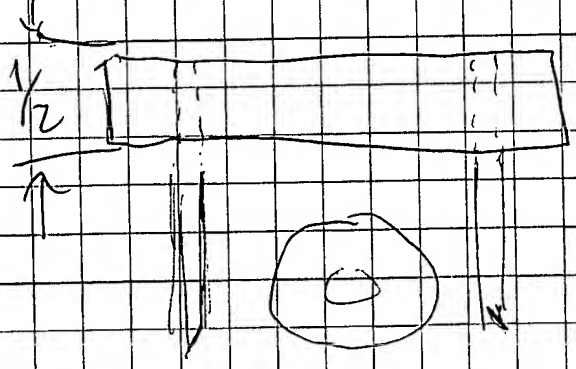
- Balloons with barium,

5/15/03

- Goal of animal testing (preliminary)
  → show a therapeutic dose in a therapeutic time.

What is required from me?

- Applicator with balloon.
- X-Ray catheter.
- Shield - Hoop with stainless steel on top.
  → Ultrasound?
- Bag for pumping saline.
  ~~Put tube on piece in line~~
  Pump tubing in line.
- Dosimeters from Landauer?
  → special for one day
- Shield? In what configurations. Stainless top.
- Template? What does it look like?



5/15/03

SAB - Follow up #2

- Steve's writing on computer.
  → Applicator length

- Balloon backstop?

5/28/03

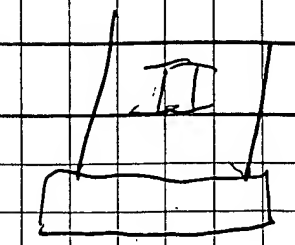
Post Dry Run Animal Study Download

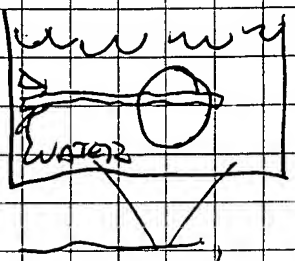
To Do's

- Hair dryer modification
- Modify template
  - → thin outer ring
  - → enlarge holes
  - →
- Dremark x-Ray catheters for tube location
- Radio opaque marker on ballon
  - → call Accuson & see if they can send some of the marking material.
  - → Barium loaded balloons

EXHIBIT R

6/12/03



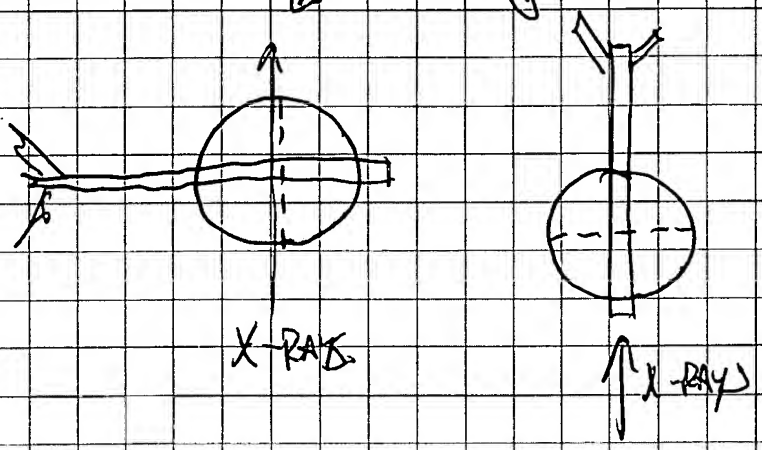


Cylchron

Applicator Balloons

Trial #1 ~~#~~ 40cc Saline + outside marking

Image #1 & #2



Trial #2 40cc Saline (0.9%) - inside marking.

Image #3

Trial #3

A .1 cc of contrast in 40cc .9% sodium Chloride

B Add 0.1 contrast + 2cc. Saline

C Add 0.2 contrast + 2cc Saline

6/17

Meeting with Robert Bley

- Extrusioneering
- Accusil
  - balloons
  - review shots on C-Arm
- summarize SAB & animal study

20% by weight tantalum in RTV
→ our samples

- discussed printing (silk screening)
  - balloon
  - drainage

6/18

- Meet with Stellartech regarding hub / interconnection to arm (console)

→ Applicator / X-Ray Catheter to do's

Applicator
- hub printing (start?)
- connector to X-Ray Cath. connector (custom? O.T.S.)
- hub color (white)?
- luer valves, both locking?
- balloon sizes (start working on 3-6 cm?)
- extrusion size (enlarge it?)
- balloon stiffener

→ X-Ray catheter
- 2 single lumens?
- custom hub?
- lengths.
- connector

→ inflate
Infl.

→ drainage
drain

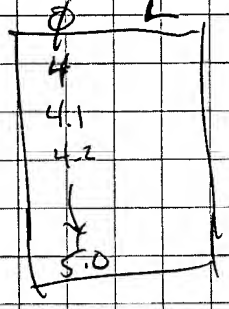
→ Shorting down of the hub

7/8/03

- Balloon shapes.

→ currently our device is not both a 4 & 5 cm. spherical balloon shape.

→ Measure out the Mammosite device & get true #'s.



→ Contact Accuseal & look @ new design / designs

3 & 4 cm	4 & 5 cm	5 & 6 cm
Spherical (same balloon)	Spherical (same balloon)	Spherical (same balloon)
	4 dia ellipsoidal	6 length

→ contrast
→ shapes
→ clean up & do labeling
→ [illegible]

7/9/03

Applicator to do items

→ Balloon Drawings: More shapes
→ Printing (Markings)
→ Contrast info. tests
→ Pull Back arm rests

- Molded parts due when? from Accusil for 50 hubs & endcaps. (7/15/03)

- Prototype / clinical units is current concept of Sorc connector call Sean

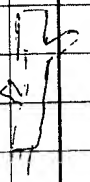
- Get dwgs out to build. I need a P.O. ✓

- Order Halkey Valves. ✓

→ Phone call w/ Accusil discussion of balloons with ribs & variable thicknesses for varying inflation parameters.

7/16 Meeting w/ Stellartech

→ Give Sean Hub dimensions for X-Ray catheter



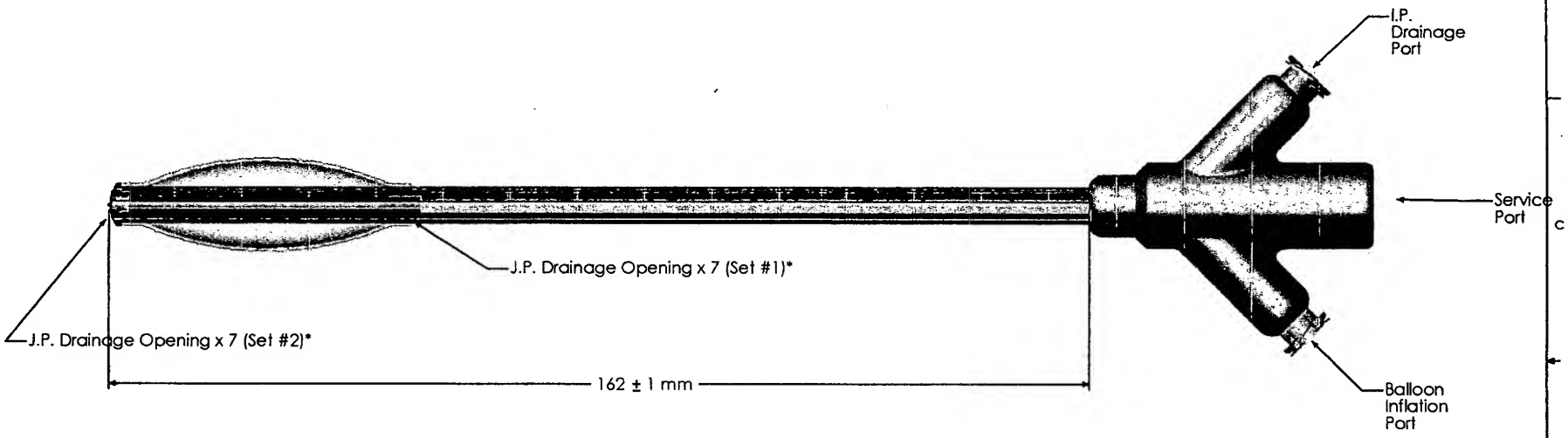
→ Send Sean all part dwgs. of Hub (applicator) I sent dwg. Hub Rev of # 71004.1.B

→ Bag vs. canister
- ⇒ Qty. of fluid.
- ⇒ Bag design
  - ⇒ spike into another bag
  - ⇒ connect with luer?
  - ⇒ Dual tubing.

order Mc Master parts
- ⇒ quick release
- ⇒ tubing (dual)
- ⇒ stopper - ?

Meeting in house on console
T, R, M, St, P, D, H
- ⇒ Schedule
- ⇒ Animal Study ready prototypes
- ⇒ Testing with all different sizes of balloons. (3, 4, 5, oblong ?)

REVISIONS				
REV.	ECO#	DESCRIPTION	DATE	APPROVED



* J.P. Drainage opening sets are in fluid communication

Reference MP 0035

Bill of Material

710011	Applicator shaft	1
710008	Applicator shaft stiffener	1
710004	Applicator end hub	1
710005	Applicator balloon - round	1
710007	Applicator end plug	1
710021	Balloon inflation valve	1
710022	J.P. Drainage valve	1
xxxxxx	Applicator proximal connector	1
710019	Silicone adhesive	AR

NEXT ASSY	USED ON

THIS DRAWING HAS BEEN GENERATED AND IS MAINTAINED BY A SOLIDWORKS CAD SYSTEM

DO NOT MANUALLY UPDATE

PROPRIETARY AND CONFIDENTIAL

THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF Xoft microTube, Inc. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF Xoft microTube, Inc. IS PROHIBITED.

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES TOLERANCES ARE: .X ±0.1 .XX ±0.01 .XXX ±0.005 .XXXX ±0.0005 ANGULAR (±) MACHINED 0°30' FORMED 1° CHAMFER 0° MACHINED SURFACES BREAK SHARP EDGES .001 or .02 x 45 MAX

PROJECTION

MATERIAL

FINISH

APPROVALS	DATE
DRAWN Alex Lim	07/17/03
CHECKED	
RESP ENG	
MFG ENG	
QUAL ENG	

DO NOT SCALE DRAWING

INTERPRET DIMENSIONING AND TOLERANCING PER ANSI Y14.5M

Xoft microTube

49000 Milmont Drive, Fremont, CA 94538 (510) 360-2900 Fax (510) 668-0962

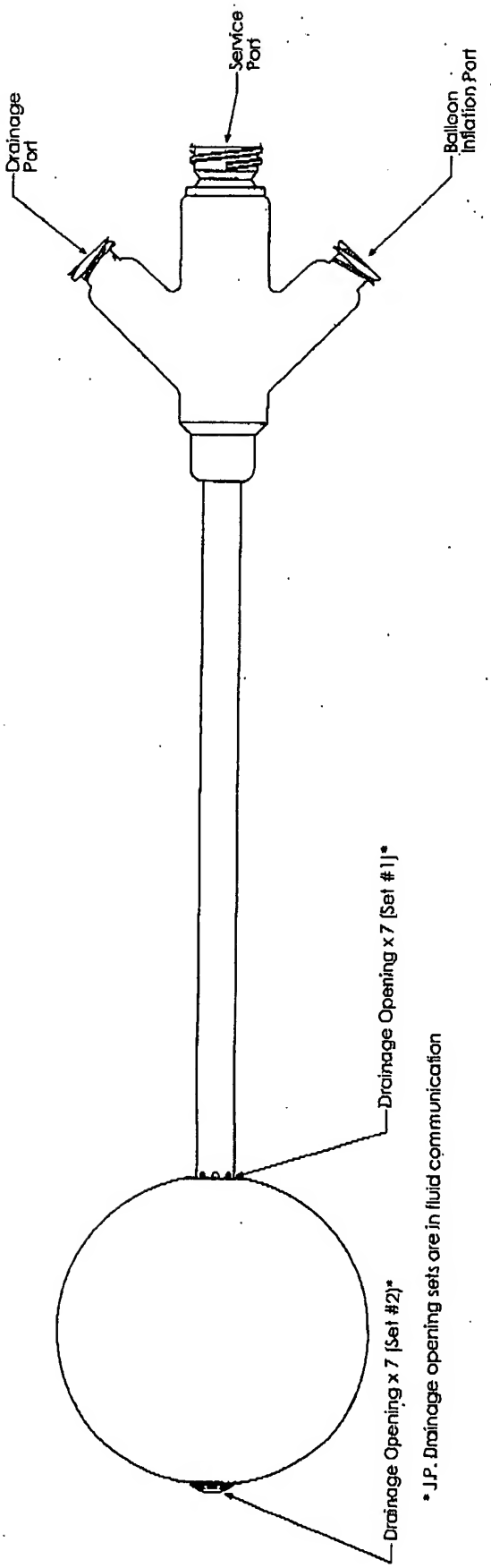
Balloon Applicator

SIZE	PART NO.	VERSION	REV.
B	710002	1	3

SCALE: 1=1 CAD FILE: SHEET 1 OF 1

EXHIBIT X

EXHIBIT Y


Service Port
Drainage Port
Balloon Inflation Port
Drainage Opening x 7 (Set #1)*
Drainage Opening x 7 (Set #2)*
* J.P. Drainage opening sets are in fluid communication

Applicator Brainstorming Meeting 7/22/2003

- Applicator with Drain
  - Current design
  - Textured balloon
  - Multiple ports

Don't to disclose more on this.

- Applicator connectors
  - Unique interaction with insertion tool
- Balloon with variable wall thickness to control shape
- Multiple balloons for shape
- Balloons with ribs for shape
- Puncture resistant balloons ?
- Bioerrodiable balloon
- Contrast material built into wall
- Contrast material in channels or volumes using multiple balloons
- Applicator with coatings
  - For aiding removal
  - To aid insertion of source
  - To reduce adhesion
  - To aid wound healing

- Applicator shaft with depth markers
- Wound management with seal
  - With drug delivery for wound healing
- Applicator with radiation ~~adsorber~~ absorber to tailor dose — under one of the ★ above
- Applicator with ability to translate source → X-Ray cath can move independently
- Applicator with high compliance
- Mesh baskets
  - Made from Nitinol
  - Made for Bioerrodiable material
  - Expansion control for basket – one size fits all
- Contrast
  - Using contrast to image and then removing for treatment
  - Using contrast with balloon cavity thickness to tailor radiation dose
- Stiffemer
  - Variable stiffness
  - Supporting balloon shape
- Balloon expansion limiter for size control → Paul → cigar band idea.

EXHIBIT AA

7/22

Applicator Patent Submission Mtg.

→ Generate a list of all possible features that could be incorporated in our device

→ A full list of thoughts was created & will be investigated by Paul L. as part of a full patent submission.

7/25

Applicator Balloon Measurements
with water
20 Durometer Balloon 4-5 cm.
Mounted on standard extrusion.

Volume	∅ @ Midpoint	L
30 cc	38.4 mm	41.3
35 cc	40.1	42.2
40 cc	41.8	43.4
45 cc	43.9	43.9
50 cc	45.5	45.0
55 cc	46.9	45.8
60 cc	48.3	46.3
65 cc	49.4	47.7
70 cc	50.7	48.0
75 cc	51.7	49.0

8/13.

→ Ask Cheryl for complaint letter response.

→ Animal testing. [8 animals]

Multiple shaped balloons.

→ Implant devices on 18th or 19th of Sep.

3-4	3	8
4-5	4.5	8
5-6	6	8
Oblong (Elliptical)		8

of each

→ Human studies

3-4	100
4-5	200
5-6	100
oblong	100

Quantities

8/14/03 Thursday

- Animal Study ~~#~~3 Preparation Meeting
  - discussion of GLP vs. non GLP
- ☐ get a copy of FDA submission document
- current treat week is Sept. 22-26

4 things need to get done

1. Applicator 4 sizes
   a) 3-4
   b) 4-5
   c) 5-6
   d) elliptical

→ We are now talking about using a 3, 4.5, 6 sphere as our data point.

→ Balloons should have barium loading (3%)

- N/A We need to get a bag sealer/pouch sealer

2. System

→ power to tube
→ pullback

3. X-Ray Sources

→ anodes
→ fixture (angle)

8/14/03 cont'd

4. Infrastructure necessary to do all the work
   - → equip.
   - → manpower
   - →

- [x] • order more parts from Accusil
  - → hubs, caps, extrusion, balloons (4 sizes, __D, 7o Bard
  - ? timing

Lynn Sages & Thurs. Night or Friday morning focus group in Chicago

- [x] • coating schedule
- [x] • sterilization schedule (Gamma)
- [ ] • Fabricate 3 obturators
  20 stylets

S	M	T	W	Th	F	S	
~~10~~	~~11~~	~~12~~	~~13~~	~~14~~	15	16	order everything necessary • Accusil • Paragon
17	18	19	20	21	22	23	
24	25	26	27	28	29	30	
31	1	2	3	4	5	6	

Aug

8/29

Balloon Applicator Hazard Analysis.

→ Infection or fever
- non-sterile
- reaction to material

→ Device becomes dislodged
- balloon ruptures
- fluid leaks out of balloon
- " " " " valve
- shaft gets kink or tear

→ Seroma in center lumen
- tip becomes detached
- fluid leak from drainage holes into center lumen

→ Tip falls off
- Bad bond joint
- Excessive obturator force in insertion
-

→ User mixes up ports accidentally drains balloon, or pushes saline into cavity
- NB unmarked
- port valves reversed.
-

~~Old coated~~ (9/3)

Stiffener damage -

Stretchiness

Balloon

- doesn't inflate to right size
- ruptures
- splits

- Clogging
  - drainage lumen
  - balloon lumens
  -

- Patient discomforts
  - too long
  - uncomfortable
  - large hub poking in ribs

- Valves coming out
- Fluid migration into or out of balloon -

9/8

Accusil agenda.

stiffener

⇒ thicker shaft
⇒ material mixing
⇒ balloon sizes
⇒ thickness of material
⇒ if we go larger can we keep same ϕ balloon collar
⇒ core pin for inflation valve
⇒ window for grabbing on lumen tubing

Lee W. cell

(858) - 692 - 0059

(714) 993 - 4100

9/10 1st day goat #3

- Smaller breasts
  - ⇒ Isoflurane (gas used)
  - → slight sedation, then gas
  - ⇒ treat & image on back
  - → Placement

→ We are placing @ 2.5% Barium filled balloon 4-5 cm.

→ Placement needs to be @ a little more of a higher angle

⇒ 4-5 cm balloon filled with 37cc + 2cc with contrast

→ Elliptical balloon has 100 cc with 3cc contrast.

~~Sizes~~

4-5cm we removed 15cc
elliptical " " 30cc.

9/11

Back @ Lychron

- Animal slightly warm to the touch.
- Both balloons were still inflated to same degree.

→ Pt back in 15 cc to round & 30cc to the elliptical 4-5 cm Balloon

→ Ultrasound views

- .86 cm thinnest area
- → 4 cm in diameter

@ elliptical

ϕ 4.71

L ? see images from Zehm

9/12

Lychrun-

Checked goat in morning. She was alert, not playing with tubes. Eating well.

Approx. 30 minutes using gas to get her from standing into the treatment room.

Warmth about the same as yesterday. Tissue looks good. 37.7°C

→ Discharge catheter. Make one or 2 catheters that we can use to discharge full energy @ the end of each treatment. If all works well, we could end up with 80 data points of worst case failure.

- Images taken & stored.

Drawing balloon to measure volume.

39 cc removed from spherical
≅ 40-41 cc inserted

75 cc removed from elliptical

→ We will need 16 stylets sterile for study.